CONFERENCE 7-8 February 2017 * COPENHAGEN

NEWS, KNOWLEGDE, EXPERIENCE & INSPIRATION

eCTD

– a practical perspective

eCTD v4.0 and Beyond

eSUBMISSION ROADMAP – EU & US

TRANSITION FROM PAPER TO eCTD – change management

AGENCY RESPONSE

OUTSOURCING OF eCTD

GLOBAL eCTD

SPEAKERS REPRESENTING:

Danish Medicines Agency (DK) * Finnish Medicines Agency (FI) * Medicines and Healthcare Products Regulatory Agency (UK)* Boehringer Ingelheim (D) * Novo Nordisk (DK) * Hansa Medical (SE) Symphogen (US) * Ferring Pharmaceuticals (DK) * Bridge Regulatory Affairs (US) * NNIT (DK)

In cooperation with

IWA Consulting Aps

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COBIS
Copenhagen Bio Science Park

medicon valley alliance
Creating Opportunities

relevent*

Speakers

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eCTD – a practical perspective

PROGRAM February 7, 2017

08.30-09.00	**Registration** *Morning Coffee*
09.00-09.05	**Welcome** *Relevent ApS*
09.05-09.10	**Chairman's Opening Remarks** Conference Chair: *Managing Partner, Head R&M Development* ***Lillan Rejkjær,*** *IWA Consulting ApS (DK)*

eSUBMISSION ROADMAP

09.10-09.40	**eCTD v4.0 and Beyond** **– Strategies to Deal with the Future of eCTD** Recently certain regions have started to introduce the RPS (Regulatory Product Submission) standard for the next generation eCTD (v4.0) into their existing current specifications. How transformative is this upcoming version of eCTD? • New perspectives and challenges with eCTD v4.0 • The regulators' intention with eCTD v4.0 • eCTD v4.0 and its relations to other Regulatory Affairs challenges such as ISO IDMP • Preparing for eCTD v4.0 and its context *Global Regulatory Affairs Lead, Managing Consultant,* ***Ph.D. Niels Buch Leander,*** *NNIT A/S (DK)*
09.40-09.50	**BREAK**
09.50-10.20	**eSubmission Roadmap – EU & EU Countries** • EU – status, when is it mandatory and where? *Special Adviser* ***Mickel Hedemand,*** *Danish Medicines Agency (DK)*
10.20-11.00	**eSubmission Roadmap – EU & EU Countries** • What is the impact on the industry? *Head of Global Submission Services,* ***Dr. Melanie Ruppel,*** *Boehringer Ingelheim (DE)*
11.00-11.15	**BREAK**
11.15-12.00	**eSubmission Roadmap – US** • FDA Forms and electronic signature • Electronic submission gateway *CEO* ***Bridgette Kunst,*** *Bridge Regulatory Affairs, LLC (US)*
12.00-13.00	**LUNCH**
13.00-13.40	**CESP/EMA Gateway and Future Repositories** • What is coming – where are we heading? • PSUR repository • Common Repository *Director, Information Resources* ***Juha-Pekka Nenonen,*** *Finnish Medicines Agency (FI)*
13.40-13.50	**BREAK**

CHANGING ENVIRONMENT

13.50-14.30	**New EMA Policy On Transparency (0070) & eCTD Submission (Redacted Clinical Data)** • What will be closed off from the public (also by eCTD)? • Publication of clinical reports *RA Senior Project Manager* ***Helle Ainsworth,*** *Novo Nordisk A/S (DK)*
14.30-14.45	**BREAK**
14.45-15.30	**Automation in Regulatory Documentation** • Options for automation of creation and maintenance of regulatory documentation • How to automate the harmonization of regulatory eCTD documents with data-based submissions such as IDMP and CTA *Principal Consultant* ***Mette Bugge,*** *NNIT A/S (DK)*
15.30-15.40	**BREAK**
15.40-16.25	**eAF - Data Reuse in other Connections (e.g. IDMP)** • Status • eCTD impact on application form (EU & US) • Application form – IDMP - How do the authorities use the data? - The ability of the authorities to draw data from eAF *Special Adviser* ***Mickel Hedemand,*** *Danish Medicines Agency (DK)* *CEO* ***Bridgette Kunst,*** *Bridge Regulatory Affairs, LLC (US)*
16.25-16.30	**Chairman's Closing Remarks**
16.30	**End of Conference Day**

eCTD – a practical perspective

PROGRAM February 8, 2017

08.30-09.00 Registration
Morning Coffee

TRANSITION FROM PAPER TO eCTD

09.00-09.40 Change Management
- How to engage the organisation?

RA Senior Project Manager ***Helle Ainsworth,*** *Novo Nordisk A/S (DK)*

09.40-09.50 BREAK

09.50-10.25 Applications in eCTD – Transition from Paper to eCTD
- What have we done, which considerations, experiences?
- How has the company been prepared for the future of only eCTD?

TBA

10.25-11.00 Submission of First eCTD
- Plan your documentation - when you start, start right

Senior Project Manager, Principal Scientist ***Åsa Schiött,***
Hansa Medical AB (SE)

11.00-11.15 BREAK

AGENCY PERSPECTIVE

11.15-12.00 Agency Response
- Receipt, registration and handling of an eCTD (clear references, file naming)
- Typical eCTD/validation issues/errors from an agency point of view

Delivery Manager ***Rachel Hyde,***
Medicines and Healthcare Products Regulatory Agency (UK)

12.00-13.00 LUNCH

OUTSOURCING OF eCTD

13.00-13.40 Outsourcing af eCTD – Smaller Companies
- What to be aware of?

Head of Regulatory Affairs, Associate Director ***Meghan Brown,***
Global Regulatory Affairs, Symphogen (US)

13.40-14.20 Outsourcing of eCTD – Larger Companies
- What to be aware of?
- In-house consultants for project specific compiling?
- Compiling at a Consultancy company?

TBA

14.20-14.35 BREAK

GLOBAL eCTD

14.35-15.15 Comparison of eCTD by Regions
Implementation of eCTD is evolving with different speeds and frequencies in different Regions. For global pharmaceutical companies this development is a business processes challenge in the context of submission, publishing and validation.
- Which are the most important differences?
- How to overcome the challenge?

TBA

15.15-15.25 BREAK

15.25-16.05 Global Submissions
Regulatory Affairs Manager ***Lise Laurbjerg Nielsen,***
Ferring Pharmaceuticals A/S (DK)

16.05-16.15 Chairman's Closing Remarks

16.15 End of Conference

PRACTIAL ISSUES

WHERE
COBIS - Copenhagen Bio Science Park, Ole Maaløes Vej 3, DK-2200 Copenhagen N, phone +45 70 70 29 80.

WHEN
Tuesday 7 February and Wednesday 8 February 2017.

WHAT

	Registration before Jan. 6 2017	Registration from Jan. 6 2017
Conference:	DKK 6.995 (excl. VAT)	DKK 7.495,- (excl. VAT)

The registration fee includes conference delegate material, refreshments and lunches.

Feel free to contact us, if one or more of your colleagues are interested too.

Members of MVA and COBIS get a discount, please remember to inform us about your membership when you register.

HOW
Registration on info@relevent.dk or +45 28305445/ +45 41951429.

Cancellations must be in writing on info@relevent.dk and will be subject to a cancellation fee.
Cancellation fees before January 24 2017 - 10% of registration fee.
Cancellation fees before February 5, 2017 - 50% of registration fee.
Cancellation fees from February 5, 2017 – no refund, thus 100% of registration fee.

To avoid cancellation fees – you may transfer your registration to a colleague. Please inform Relevent prior to the conference on info@relevent.dk.

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